EXHIBIT 2
510(k) Summary

JUL 10 2008

K073074
KaVo Dental Corporation
340 East Main Street
Lake Zurich, Illinois 60047
Toll Free: 800 323 8029
Tel: 847 / 550 - 6800
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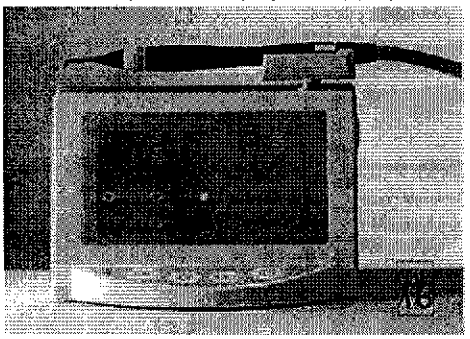
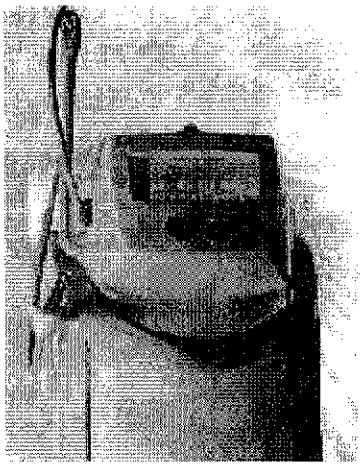
e-mail: info@kavousa.com
Contact: Mari Lambert, Director of RA/QA
July 9, 2008

1. Identification of the Device:
   Proprietary-Trade Name: KEY Laser III 1243 US without Feedback, with Detect
   Classification Name: Laser Surgical Instrument: Product Code GEX with Laser Fluorescence Caries Detection Device, Product Code NTK
   Common/Usual Name: Surgical laser with laser fluorescence caries detection device

2. Equivalent legally marketed device: K030146 Kavo Key Laser combined with K983658/ K042394/ K051909/ K060080 (Diagnodent®)

   Indications for Use (intended use): For removal of subgingival calculi in periodontal pockets with periodontitis by closed or open curettage.
   Removal of subgingival calculi in periodontal pockets which have been affected by periodontitis, with open or closed curettage and using the detection function of the KEY Laser 1243.

3. Description of the Device: This device represents the combination into one device of two previously cleared devices, the Diagnodent Laser Fluorescence Caries Detection Device with the KEY Laser III 1243.

Predicate DIAGNOdent® 2095 K983658/ K042394/ K051909/ K060080.	KEY Laser III 1243 US without Feedback, with Detect
	

4. Safety and Effectiveness, comparison to predicate device: The indications for use and the applied standards have not changed, nor has the performance of the individual devices changed as a result of combining two devices into one package. Laboratory testing has revealed that the performance of the detection function and the performance of the laser surgical functions have not changed.

5. Conclusion: In all important respects, the KEY Laser III 1243 US without Feedback, with Detect is substantially equivalent to the individual predicates. This conclusion is based on indications for use, bench, and in-vitro studies, as well as EMC and electrical safety testing. KEY Laser III 1243 US without Feedback, with Detect meets the US Performance Standard for Lasers. The device has been tested in accordance with:
   - IEC 601-1/VDE 0750 Part 1
   - ISO 7494
   - IEC 825-1 / DIN-VDE 0837 Part 1
   - VDE 0750 Part 2-2
   - Regulations 21 CFR 1040
   - ANSI Z 136.1
   - ANSI Z 136.3
   - UL Std No 60601-1 (1st Edition)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

KaVo America Corporation
% Kamm & Associates
Mr. Daniel Kamm, P.E.
340 East Main Street
Lake Zurich, Illinois 60047

JUL 10 2008

Re: K073074
Trade/Device Name: KEY Laser III 1243 US without Feedback, with Detect
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 9, 2008
Received: June 11, 2008

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073074

Device Name: KEY Laser III 1243 US without Feedback, with Detect

Indications For Use:
For removal of subgingival calculi in periodontal pockets with periodontitis by closed or open curettage.
Removal of subgingival calculi in periodontal pockets which have been affected by periodontitis, with open or closed curettage and using the detection function of the KEY Laser 1243..

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Meeks

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073074